From: Nassif, Julianne (DPH)

Sent: Monday, December 06, 2010 10:16 AM **To:** Piro, Peter (DPH); Salemi, Charles (DPH)

Subject: RE: GHB

We will meet again on this next week (as we have the CLIA inspectors here this week) and I can't become entangled in the GHB situation until they are gone. It is clear to me that the current methodology needs improvement and it needs to be standardized. We will not report any more GHB samples until we resolve this matter.

I will send a meeting request for next week.

Julie

From: Piro, Peter (DPH)

Sent: Monday, December 06, 2010 9:59 AM **To:** Nassif, Julianne (DPH); Salemi, Charles (DPH)

Subject: GHB

Hi Julie and Chuck

If you have another meeting with Mike about GHB please discuss concentration. I've tried to stress the importance of submitting standards/samples normalized to a 1 mg/mL concentration. In doing so, GC/MS can select an appropriate split ratio for the GHB method that allows a margin of error for both strong and weak samples. When Mike screened his samples, he made 0.07% GHB/GBL/ and 1,4-butanediol standards in water. That was close enough to 1mg/mL (0.1%) so I didn't say anything. Then he moved onto derivatizing the standards and samples. If he had stock solutions for each standard, he would dry down 1 mL of each standard and then add BSTFA and acetonitrile. After derivatizing, the final volume would be brought back to 1 mL so the concentration remained at 1 mg/mL. Mike submitted all the standards in 0.1 mL residue vials, leaving me to wonder what the concentration really was. I'm glad he's not working with 1-2 % solutions anymore but I'm not sure if he's following through with the 1mg/mL concept either.

On the topic of derivatizing, we all seem to agree BSTFA derivatization with acetonitrile does not always work well. Before we get rid of this method we should try derivatizing the standards without acetonitrile and then move onto samples if that techniques works.

My last concern has to do with creating an environment where people can openly communicate. I've asked for his protocol but he will not present it to me. I've made numerous attempts to talk to him but his pride prevents meaningful discourse. When I explain my concerns he reminds me of how long he's been doing this. At the same time, he doesn't want to take responsibility for the GC/MS confirmatory work. I'm trying my best to help him but he will not listen. I'm sure he listens to you both so I will take my concerns to my supervisors.

Chuck, let me know what to do with the last batch of samples that screened negative.